IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wouter E. Roorda	Examiner: Carlos A. Azpuru
Serial No.: 10/619,727	Art Unit: 1615
Filed: July 15, 2003	Confirmation No.: 7043
Customer No.: 45159	Attorney Docket No.: 050623.00211
Title: Medicated Coatings For Implantable Medical Devices Having Controlled Rate of Release	

Mail Stop **Issue Fee**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 C.F.R. § 1.312

Sir:

Applicants respectfully request that the Examiner permit the entry of this amendment under 37 C.F.R. § 1.312 to make minor amendments to some of the claims. This amendment is being filed concurrently with the payment of the issue fee.

Amendments to the Claims are reflected in the listing of claims which begins on page 2.

Remarks begin on page 7.

OK TO ENTER: /C.A./

12/14/2010

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of the claims in the application:

Listing of Claims:

1. (Currently Amended) A coating for an implantable medical device, the coating comprising a first region comprising a polymer and a drug incorporated therein and a second region disposed over the first region,

wherein the second region comprises a polymer and a material having a melting temperature within the range between about 32 °C and 40 °C for modifying the rate of release of the drug, the polymer in the second region having in a dry state a glass transition temperature within a range of about 35 °C and about 50 °C,

wherein the polymer in the second region in the dry state contains less than about 1 mass % of water, and

wherein when the body temperature of a patient in which the implantable medical device comprising the coating is implanted rises to a temperature above the patient's normal body temperature, the morphology of the coating changes so as to change the release rate of the drug in the coating.

2. (Original) The coating of Claim 1, wherein the implantable medical device is a stent.

3. (Original) The coating of Claim 1, wherein the drug is an anti-inflammatory drug.

4. (Previously Presented) The coating of Claim 1, wherein the polymer in the second region, the polymer in the first region, or both polymers in the first and the second regions comprise an acrylic polymer, a non-acrylic polymer, or blends thereof.

5. (Cancelled)

6. (Currently Amended) The coating of Claim 4, wherein the non-acrylic polymer is selected from [[a]]the group consisting of poly(2-cyclohexylethylethylene), atactic poly(*iso*-propylethylene), poly(1,1,2-trimethylethylene), poly(4,4 dimethylpentylethylene), poly(2,2,2-trifluoroethoxytrifluoroethylene), poly(4-methoxybenzoylethylene), poly(3,4-dimethoxybenzoylethylene), poly(vinyl fluoride), poly(cyclopentanoyloxyethylene), 60% syndiotactic poly(formyloxyethylene), poly[4-(*sec*-butoxymethyl) styrene], poly(4-butoxystyrene), and blends thereof.

7. (Cancelled)

8. (Previously Presented) The coating of Claim 1, wherein the polymer in the second region has a melting temperature above about 50 °C.

9. (Currently Amended) A topcoat for an implantable medical device, comprising a first phase comprising a polymer, and a second phase comprising a material immiscible with the polymer, the material having a melting temperature within the range between about 32 °C and 40 °C,

wherein when the body temperature of a patient in which the implantable medical device comprising the topcoat is implanted rises to a temperature above the patient's normal body temperature, the morphology of the topcoat changes so as to change the release rate of a drug in a coating under the topcoat.

10. (Previously Presented) The topcoat of Claim 9, wherein the implantable medical device is a stent.

11. (Previously Presented) The topcoat of Claim 9, wherein the material has a melting temperature of about 37 °C.

12. (Previously Presented) The topcoat of Claim 9, wherein the polymer comprises an acrylic polymer, a non-acrylic polymer, or blends thereof.

13. (Cancelled)

14. (Cancelled)

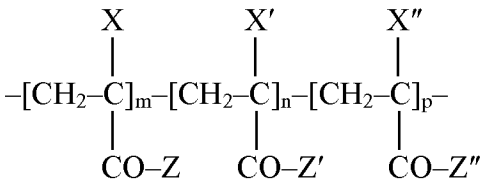
15. (Currently Amended) The topcoat of Claim 12, wherein the non-acrylic polymer is selected from [[a]]the group consisting of poly(2-cyclohexylethylethylene), atactic poly(*iso*-propylethylene), poly(1,1,2-trimethylethylene), poly(4,4 dimethylpentylethylene), poly(2,2,2-trifluoroethoxytrifluoroethylene), poly(4-methoxybenzoylethylene), poly(3,4-dimethoxybenzoylethylene), poly(vinyl fluoride), poly(cyclopentanoyloxyethylene), 60% syndiotactic poly(formyloxyethylene), poly[4-(*sec*-butoxymethyl) styrene], poly(4-butoxystyrene), and blends thereof.

16. (Previously Presented) The topcoat of Claim 9, wherein the drug is an anti-inflammatory drug.

17. – 24. (Cancelled)

25. (Currently Amended) The coating of Claim 4, wherein the acrylic ~~polymers are~~ polymer is selected from [[a]]the group consisting of poly(*tert*-butyl acrylate), poly[3-chloro-2,2-*bis*(chloromethyl) propyl acrylate], poly(cyanobenzyl acrylate), poly(2-methoxycarbonylphenyl acrylate), poly(3-methoxycarbonylphenyl acrylate), poly(4-ethoxycarbonylphenyl acrylate), poly(hexadecyl acrylate), poly(3-dimethylaminophenyl acrylate), poly(*p*-tolyl acrylate), poly(*n*-butyl acrylamide), poly(*iso*-decyl acrylamide), poly(octafluoropentyl methacrylate), poly(3,3-dimethylbutyl methacrylate), isotactic poly(methyl methacrylate), poly(*n*-propyl methacrylate), isotactic poly(ethyl chloroacrylate), poly(ethyl fluoromethacrylate), and blends thereof.

26. (Currently Amended) The coating of Claim 4, wherein the acrylic ~~polymers are~~ polymer is of the formula



(I)

wherein:

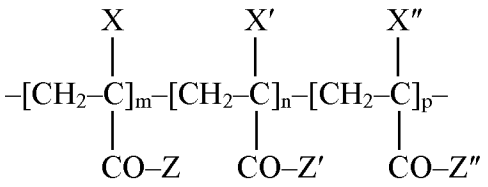
X, X′, and X″ is each, independently, a hydrogen atom or an alkyl group~~, such as methyl group~~;

Z, Z′, and Z″ is each, independently, a substituted or unsubstituted amino group or an alkoxy group OR, OR′, and OR″, where R, R′ and R″ is each, independently, a C_1 to C_{12} straight chained or branched aliphatic radical; and

each of m, n, and p is an integer, where $m > 0$, $n \geq 0$, and $p \geq 0$.

27. (Currently Amended) The ~~coating~~topcoat of Claim 12, wherein the acrylic ~~polymers are~~polymer is selected from [[a]]the group consisting of poly(*tert*-butyl acrylate), poly[3-chloro-2,2-*bis*(chloromethyl) propyl acrylate], poly(cyanobenzyl acrylate), poly(2-methoxycarbonylphenyl acrylate), poly(3-methoxycarbonylphenyl acrylate), poly(4-ethoxycarbonylphenyl acrylate), poly(hexadecyl acrylate), poly(3-dimethylaminophenyl acrylate), poly(*p*-tolyl acrylate), poly(*n*-butyl acrylamide), poly(*iso*-decyl acrylamide), poly(octafluoropentyl methacrylate), poly(3,3-dimethylbutyl methacrylate), isotactic poly(methyl methacrylate), poly(*n*-propyl methacrylate), isotactic poly(ethyl chloroacrylate), poly(ethyl fluoromethacrylate), and blends thereof.

28. (Currently Amended) The ~~coating~~topcoat of Claim 12, wherein the acrylic ~~polymers are~~polymer is of the formula



(I)

wherein:

X, X′, and X″ is each, independently, a hydrogen atom or an alkyl group~~, such as methyl group~~;

Z, Z′, and Z″ is each, independently, a substituted or unsubstituted amino group or an alkoxy group OR, OR′, and OR″, where R, R′ and R″ is each, independently, a C_1 to C_{12} straight chained or branched aliphatic radical; and

each of m, n, and p is an integer, where $m > 0$, $n \geq 0$, and $p \geq 0$.

29. (Currently Amended) The coating of Claim 1, wherein the material is selected from the group consisting of 1-tetradecanol, Vegetable wax, Cocoa butter, and Triglyceride (stearin-dipalmityl).

30. (Currently Amended) The topcoat of Claim 9, wherein the material is selected from the group consisting of 1-tetradecanol, Vegetable wax, Cocoa butter, and Triglyceride (stearin-dipalmityl).

Remarks

Amendments to the Claims

The Examiner has allowed claims 1 – 4, 6, 8 – 12, 15, 16, and 25 – 30.

Claims 1, 6, 9, 15, and 25 – 30 have been amended.

Claims 1 and 9 have been amended to clarify antecedent basis by amending "device" to "implantable medical device."

Claims 25, 26, 27, and 28 have been amended to recite "acrylic polymer is" rather than "acrylic polymers are" to make these claims consistent with claims 4, 6, 12, and 15. Claims 27 and 28 have additionally been amended to clarify antecedent basis.

Claims 6, 15, 29, and 30 have been amended to a more traditional Markush format.

No new matter has been introduced, and no new issues have been raised by these claim amendments.

Comments on Statement of Reasons for Allowance

Responsive the Notice of Allowance and Fee(s) Due mailed on August 6, 2010, while Applicants believe that each of claims 1 – 4, 6, 8 – 12, 15, 16, and 25 – 30 is allowable, Applicants do not acquiesce that patentability resides in each feature, exactly as expressed in each of the claims, nor that each feature is required for patentability.

Conclusion

Applicants respectfully request the entry of this amendment under 37 C.F.R. § 1.312 after the issuance of a Notice of Allowance.

If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0397.

Respectfully submitted,

Dated: Monday, November 08, 2010

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